K091558

JUL 17 2009

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by §807.92

Device Name – as required by 807.92(a)(2):

Trade Name:	**BioVision Digital Specimen Radiography (DSR) System**
Common/Classification Name:	**Specimen X-ray System/Cabinet, X-ray System**
Classification Regulation:	**21 CFR § 892.1680**
Device Class:	**Class II**
Product Code (Procode):	**MWP**
Panel:	**Radiologic Devices Panel**

Premarket Notification submitter: Company Name:	**Bioptics, Inc.**
Company Address:	**3440 E. Britannia Dr. Suite 150** **Tucson Az, 85706**
Contact:	**Carlos Reyes, Quality Engineer**

Preparation Date:	May 2009

A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)

The **BioVision Digital Specimen Radiography (DSR) System** is substantially equivalent to the **piXarray 100 Digital Specimen Radiography System**, manufactured by Bioptics, Inc. as a cabinet X-ray system, **K052433**.

B. DEVICE DESCRIPTION – as required by 807.92(a)(4)

The **BioVision Digital Specimen Radiography (DSR) System** is a stand-alone cabinet digital X-ray imaging system to provide rapid verification that the correct tissue has been excised during percutaneous biopsy.

Performing the verification directly in the same biopsy procedure room enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls.

The **BioVision Digital Specimen Radiography (DSR) System** employs the use of **Bioptics Vision** image acquisition software. The **Bioptics Vision** software handles the digital X-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving, and transmittal. **Bioptics Vision** software is the central part of this system. **Bioptics Vision** software is Digital Imaging and Communications in Medicine (DICOM) 3.0 compliant and comes with DICOM Print, Store and Modality Work List (MWL).

C. DEVICE CLAIMS - as required by 807.92(a)(4)

The **BioVision Digital Specimen Radiography (DSR) System** is of compact and portable design plugs into any A/C outlet and requires no external X-ray shielding. The **Core Vision DSR System** offers one-button operation utilizing automatic exposure control for optimal X-ray exposure. This device offers high resolution digital imaging with small area formats.

The **Bioptics Vision** software transfers images to Radiology and Pathology within seconds though DICOM interface.

D. PRODUCT AND TECHNICAL SPECIFICATIONS - as required by 807.92(a)(4)

The **Core Vision Digital Specimen Radiography (DSR) System** is of compact and portable design, plugs into any A/C outlet, and requires no external X-ray shielding. The **BioVision DSR System** offers one-button operation utilizing automatic exposure control for optimal X-ray exposure.

The **Bioptics Vision** software handles the digital X-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving, and transmittal. **Bioptics Vision** software is the central part of this system. **Bioptics Vision** software is Digital Imaging and Communications in Medicine (DICOM) 3.0 compliant and comes with DICOM Print, Store and Modality Work List (MWL). The **Bioptics Vision** software transfers images to Radiology and Pathology within seconds though the DICOM interface.

Below is a specifications chart of the Predicate Device with the Core Vision DSR System.

	Specifications
Automatic kV Option	Included
Automatic Exposure Time Option	Included
Manual Exposure Time Selection	Included
Geometric Magnification	Included
One-Button Calibration	Included
Energy Range	5-45 kV
Tube Current	1.0 mA
X-ray Coverage	11.2 cm
External X-ray shielding	Not required
Imaging Area (mm)	26 X 75 mm
Resolution (contact mode)	14 lp/mm
Focal Spot	50 um nominal
DICOM Interface (store, print, work list)	Included
Manual kV Selection	Included
Window Filtration	0.2 mm Beryllium

E. INTENDED USE - as required by 807.92(a)(5)

Bioptics defines intended use as the objective intent of the manufacturer or person(s) legally responsible for the labeling of devices and includes labeling claims, advertising matter, and approved oral or written statements by such firms or their representatives. As such, Bioptics intends its advertising matter, specifications, user manual and other written or authorized oral statements to identify the objective intent of the Bioptics.

Bioptics intends that the submitted device's intended uses include, but are not limited to, the following:

- Uses typical of those for "cabinet x-ray" or "specimen x-ray" devices.
- A device intended to generate and control x-rays for examination of various anatomical regions.
- A device intended to provide rapid verification, through x-ray examination, that the correct tissue has been excised during percutaneous biopsy.
- A device intended to create an x-ray image of biopsy material, including in the biopsy procedure room or wherever medical professionals deem appropriate, to enable the rapid x-ray examination of the biopsy specimen and the rapid verification that the correct specimen was excised.

F. INDICATIONS FOR USE

The **BioVision Digital Specimen Radiography (DSR) System** is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of various anatomical regions, and to provide rapid verification that the correct tissue has been excised during percutaneous biopsy.

Performing the verification directly in the same biopsy procedure room enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls. This device is intended to be operated wherever the medical professionals deem appropriate, including a surgical suite or a room adjacent to a surgical suite.

G. LEVEL OF CONCERN – as requested by recent FDA guidance

Bioptics has determined that the submitted device has a "**moderate**" software **Level of Concern** and has provided that documented record as part of this submission.

H. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

The **BioVision Digital Specimen Radiography (DSR) System** has the same indications for use as the **piXarray 100 Digital Specimen Radiography (DSR) System, K052433**. The **Core Vision Digital Specimen Radiography (DSR) System** has the same technological characteristics as the **piXarray 100 Digital Specimen Radiography (DSR) System. Section III Substantial Equivalence** of this submission provides a detailed **COMPARISON MATRIX** of the predicate **piXarray 100 Digital Specimen Radiography (DSR) System** to the **Core Vision Digital Specimen Radiography (DSR) System.**

The submitter claims that the **BioVision Digital Specimen Radiography (DSR) System** is substantially equivalent to the predicate device, the **piXarray 100 Digital Specimen Radiography (DSR) System.**

The technological characteristics of the **piXarray 100 Digital Specimen Radiography (DSR) System** are very similar to those of the **Core Vision Digital Specimen Radiography (DSR) System**. The differences include:

TABLE OF DIFFERENCES BETWEEN THE piXarray 100 DIGITAL SPECIMEN RADIOGRAPHY (DSR) SYSTEM AND THE CORE VISION CABINET X-RAY SYSTEM

Characteristic	piXarray 100 DSR	BioVision
X-ray coverage	11.2 cm	19.0 cm
Imaging area (mm)	26 X 75	75 x 50, 100 x 150,120 x 180, 180 x 240
Film or Digital Imaging	Digital Only	Yes
Energy Range	5-25 kV	5-45 kV
Resolution (contact mode)	14 lp/mm (35 microns)	10 lp/mm (50 microns)
Footprint (Overall Dimensions)	36cm w x 34cm d x 39cm h	53cm w x 38cm d x 170cm h
Used for excised and percutaneous biopsy samples	Yes	Yes

The submitter concludes that the **piXarray 100 Digital Specimen Radiography (DSR) System** employs the same type of technological characteristics including X-ray technology, power source, digital imaging, computer interface for user functionality, computer hardware, operating system, and similar functionality to the **BioVision Specimen Radiography System.** The majority of differences are either not significant or relate to evolutionary changes in technology that has occurred since the release of the **piXarray 100 Digital Specimen Radiography (DSR) System.**

I. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW - as required by 807.92(b)(1)

As a cabinet or specimen X-ray device, the submitted device is required to comply with Part 1020, FDA's performance standards for ionizing radiation emitting products and specifically to 21 CFR 1020.40 Cabinet X-ray systems. The **BioVision Digital Specimen Radiography (DSR) System** conforms to 21 CFR 1020.40. Evidence of the compliance is provided throughout this submission and is referenced in the appropriate exhibits.

The radiation emitted from the **BioVision Digital Specimen Radiography (DSR) System** cabinet x-ray system does not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface. See Radiographic Control Certificate, Document # 1240 is included in this exhibit.

Additionally, the submitted device has been designed in a device design and manufacturing environment with a robust quality system.

Extremely controlled and detailed design inputs and outputs define all of Bioptics product development activities. Some of these activities include, but are not limited to, detailed design specifications, verification and validation activities, and revision history and revision documentation. An emphasis on controlled software activities include risk assessment and management, level of concern and configuration management. These activities are thoroughly documented and reviewed and approved by appropriate authorized authorities.

The submitter believes and claims that the submitted device was developed, designed, tested and validated to perform in a manner that accurately portrays the submitted systems intended use, functionality, safety features, user interface, operation, and documentation. The results of these activities were reviewed by appropriate management and that review resulted in the documented determination that the submitted device met its design plan, is safe and effective, and, subsequent to FDA review of this submission, is ready for commercial distribution as a medical device.

The submitted device's software controls were subjected to significant verification and validation testing. Verification testing was performed during software coding and results were recorded as "comments" in the software code. Alpha validation testing included testing of all functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface or documentation.

Alpha validation activities included specified system software and operating software performance and environmental testing within the specified environment. Refer to "Software Revision History", Document # 1239, included in Exhibit 9.

Additionally, a few devices, labeled "Research Use Only," are being placed to further document the submitter's performance claims and attempt to identify any unknown hazards. Any significant findings will be investigated and resolved appropriately. If a significant finding rises to an appropriate level, the submitter will take appropriate FDA notification action.

The predicate device, **piXarray 100 Digital Specimen Radiography (DSR) System** did not provide or reference any clinical tests submitted in compliance with **807.92(b)(2)**, therefore the submitter believes such clinical testing is not appropriate or required by FDA and has not made or provided any summary of such testing.

J. SUBSTANTIAL EQUIVALENCE SUMMARY

The **piXarray 100 Digital Specimen Radiography (DSR) System** has the same indications for use as the **BioVision Digital Specimen Radiography (DSR) System**. The **BioVision Digital Specimen Radiography (DSR) System** has the same technological characteristics as the **piXarray 100 Digital Specimen Radiography (DSR) System**. However, while the submitter believes the characteristics are sufficiently precise to assure equivalence, the submitter has carried out validation and performance testing to further document equivalence. The results of this testing substantiates that the **BioVision Digital Specimen Radiography (DSR) System** performs as well as the predicate, the **piXarray 100 Digital Specimen Radiography (DSR) System**.

K. CONCLUSIONS

The performance testing and validation studies document that the **BioVision Digital Specimen Radiography (DSR) System** is substantially equivalent to the **piXarray 100 Digital Specimen Radiography (DSR) System**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2009

Mr. Dung Nguyen
Vice President Engineering
Bioptics, Inc.
3440 East Britannia Drive, Suite 150
TUCSON AZ 85706

Re: K091558
Trade/Device Name: BioVision Digital Specimen Radiography (DSR) System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: May 13, 2009
Received: May 28, 2009

Dear Mr. Nguyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K091558

Device Name: **BioVision Digital Specimen Radiography (DSR) System**

Indications for Use:

The **BioVision Digital Specimen Radiography (DSR) System** is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of various anatomical regions, and to provide rapid verification that the correct tissue has been excised during excisional or percutaneous biopsy.

Performing the verification directly in the same biopsy procedure room enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls. This device is intended to be operated wherever the medical professionals deem appropriate, including a surgical suite or a room adjacent to a surgical suite.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091558